RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

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FILED

DATE: March 29, 2024
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WSR 24-08-061

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

☐ 31 days after filing.

☒ Other (specify) May 1, 2024 **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: HCA amended these rules to add clarity and provide more detail on program requirements for how fee-for-service drugs must be billed to HCA for providers that are subject to the 340B program requirements.

Citation of rules affected by this order:

New:
Repealed:
Amended: 182-530-1050; 182-530-7000; 182-530-7250; 182-550-7300; 182-530-7900; 182-530-8000; 182-530-8100; 182-531-0050; 182-531-1200; 182-531-1450
Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority: N/A

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 24-05-054 on February 16, 2024 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	____	Amended	____	Repealed	____

The number of sections adopted at the request of a nongovernmental entity:

	New	____	Amended	____	Repealed	____

The number of sections adopted on the agency's own initiative:

	New	____	Amended	____	Repealed	____

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	____	Amended	10	Repealed	____

The number of sections adopted using:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	____	Amended	10	Repealed	____

Date Adopted: March 29, 2024	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

AMENDATORY SECTION (Amending WSR 17-07-001, filed 3/1/17, effective 4/1/17)

WAC 182-530-1050 Definitions. In addition to the definitions and abbreviations found in chapter 182-500 WAC, Medical definitions, the following definitions apply to this chapter.

"340B program" - The federal program that requires drug manufacturers participating in the medicaid drug rebate program (MDRP) to provide covered outpatient drugs to enrolled "covered entities" at or below the ceiling price, as described in 42 U.S.C. § 256b. This requirement is described in section 340B of the Public Health Service Act and codified in 42 U.S.C. § 256b.

"340B provider" or **"PHS-qualified covered entity"** - Any provider including, but not limited to, a clinic, facility, hospital, pharmacy, or program listed in 42 U.S.C. § 256b as eligible to purchase, dispense, or administer outpatient drugs through the 340B program, has submitted its valid medicaid provider number(s) or national provider identification (NPI) number to the public health service (PHS), health resources and services administration (HRSA), office of pharmacy affairs (OPA), and has registered with and been approved by OPA.

"340B maximum allowable cost (340B MAC)" - The maximum amount the medicaid agency reimburses a participating 340B public health services (PHS)-qualified covered entity to purchase, dispense, or administer a covered outpatient drug, device, or drug-related supply.

"Active ingredient" - The chemical component of a drug responsible for a drug's prescribed/intended therapeutic effect. The medicaid agency or ((~~its~~)) the agency's designee limits coverage of active ingredients to those with an ((~~eleven~~)) 11-digit national drug code (NDC) and those specifically authorized by the agency or ((~~its~~)) the agency's designee.

"Actual acquisition cost (AAC)" - ((~~Refers to one of the following:~~

~~(1) Provider AAC -~~)) The true cost ((~~a provider~~)) paid for a specific drug or product in the package size purchased, including discounts, rebates, charge backs that affect the provider's invoice price, and other adjustments to the price of the drug, device, or drug-related supply, excluding dispensing fees((~~;~~

~~(2) 340B AAC - The true cost paid by a public health service (PHS)-qualifying entity for a specific drug, excluding dispensing fees; or~~

~~(3) POS AAC - The agency-determined rate paid to pharmacies through the point-of-sale (POS) system, and intended to reflect pharmacy providers' actual acquisition cost~~)).

"Administer" - Includes the direct application of a prescription drug or device by injection, insertion, inhalation, ingestion, or any other means, to the body of a patient by a practitioner, or at the direction of the practitioner.

"Appointing authority" - ((~~Means~~)) The following people acting jointly: The director of the Washington state health care authority and the director of the Washington state department of labor and industries.

"Authorized generic drug" - Any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or pack-

aging (other than repackaging the listed drug for use in institutions) than the brand name drug.

"Automated authorization" - Adjudication of claims using submitted NCPDP data elements or claims history to verify that the medicaid agency's or its designee's authorization requirements have been satisfied without the need for the medicaid agency or its designee to request additional clinical information.

((~~**"Automated maximum allowable cost (AMAC)" - The rate established by the medicaid agency or its designee for a multiple-source drug that is not on the maximum allowable cost (MAC) list and that is designated by two or more products at least one of which must be under a federal drug rebate contract.**~~))

"Average manufacturer price (AMP)" - The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.

"Average sales price (ASP)" - The weighted average of all nonfederal sales to ((~~wholesalers~~)) wholesaler's net of charge backs, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer.

"Average wholesale price (AWP)" - A reference price of a drug product that is published at a point in time and reported to the medicaid agency or its designee by the agency's drug file contractor.

"Brand name drug" – A single-source or innovator multiple-source drug.

"Compendia of drug information" - Includes the following:

(1) The American Hospital Formulary Service Drug Information;

(2) The United States Pharmacopeia Drug Information; and

(3) DRUGDEX Information System.

"Compounding" - The act of combining two or more active ingredients or adjusting therapeutic strengths in the preparation of a prescription.

"Deliver or delivery" - The transfer of a drug or device from one person to another.

"Dispense as written (DAW)" - An instruction to the pharmacist forbidding substitution of a generic drug or a therapeutically equivalent product for the specific drug product prescribed.

"Dispensing fee" - Means professional dispensing fee. See professional dispensing fee.

"Drug file" - A list of drug products, pricing and other information provided to the medicaid agency or its designee and maintained by a drug file contractor.

"Drug file contractor" - An entity which has been contracted to provide regularly updated information on drugs, devices, and drug-related supplies at specified intervals, for the purpose of pharmaceutical claim adjudication. Information is provided specific to individual national drug codes, including product pricing.

"Drug-related supplies" - Nondrug items necessary for the administration, delivery, or monitoring of a drug or drug regimen.

"Drug use review (DUR)" - A review of covered outpatient drug use that assures prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

"Effectiveness" - The extent to which a given intervention is likely to produce beneficial results for which it is intended in ordinary circumstances.

"Efficacy" - The extent to which a given intervention is likely to produce beneficial effects in the context of the research study.

"Emergency kit" - A set of limited pharmaceuticals furnished to a nursing facility by the pharmacy that provides prescription dispensing services to that facility. Each kit is specifically set up to meet the emergency needs of each nursing facility's client population and is for use during those hours when pharmacy services are unavailable.

"Endorsing practitioner" - A practitioner who has reviewed the Washington preferred drug list (Washington PDL) and has enrolled with the health care authority (HCA), agreeing to allow therapeutic interchange (substitution) of a preferred drug for any nonpreferred drug in a given therapeutic class on the Washington PDL.

"Estimated acquisition cost (EAC)" - The medicaid agency's estimate of the price providers generally and currently pay for a drug marketed or sold by a particular manufacturer or labeler.

"Evidence-based drug reviews" - The application of a set of principles and methods for comprehensive independent and objective evaluation of clinical evidence provided in well-designed and well-conducted studies and objective clinical data to determine the level of evidence that proves to the greatest extent possible, that a health care service is safe, effective, and beneficial when making population-based coverage policies or individual medical necessity decisions. Classifying evidence by its epistemologic strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations; weaker types (such as from case-control studies) can yield weak recommendations.

"Evidence-based practice center" or **"EPC"** - A research organization that has been designated by the Agency for Healthcare Research and Quality (AHRQ) to develop evidence reports and technology assessments on topics relevant to clinical and other health care organization and delivery issues, specifically those that are common, expensive, or significant for the medicare and medicaid populations.

"Federal drug rebates" - Dollars returned to medicaid from pharmaceutical manufacturers under the terms of the manufacturers' national rebate agreement with the federal Department of Health and Human Services (DHHS).

"Federal upper limit (FUL)" - The maximum allowable reimbursement set by the Centers for Medicare and Medicaid Services (CMS) for a multiple-source drug.

"Generic drug" - A drug that is approved by the Food and Drug Administration (FDA) under an abbreviated new drug application.

"Inactive ingredient" - A drug component that remains chemically unchanged during compounding but serves as the:

(1) Necessary vehicle for the delivery of the therapeutic effect; or

(2) Agent for the intended method or rate of absorption for the drug's active therapeutic agent.

"Ingredient cost" - The portion of a prescription's cost attributable to the covered drug ingredients or chemical components.

"Innovator multiple-source drug" - A multiple-source drug that was originally marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. This includes:

(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or

(2) A covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).

"Less than effective drug" or **"DESI"** - A drug for which:

(1) Effective approval of the drug application has been withdrawn by the Food and Drug Administration (FDA) for safety or efficacy reasons as a result of the drug efficacy study implementation (DESI) review; or

(2) The secretary of the federal Department of Health and Human Services (DHHS) has issued a notice of an opportunity for a hearing under section 505(e) of the federal Food, Drug, and Cosmetic Act on a proposed order of the secretary to withdraw approval of an application for such drug under such section because the secretary has determined the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling.

"Maximum allowable cost (MAC)" - The maximum amount the medicaid agency or its designee reimburses for a drug, device, or drug-related supply.

"Medicaid preferred drug list (medicaid PDL)" - The list of all drugs in drug classes approved for inclusion by the Washington medicaid drug use review (DUR) board and each drug's preferred or nonpreferred status as approved by the agency director or designee. The list includes at minimum all drugs and drug classes on the Washington PDL and may include additional drugs and drug classes recommended by the DUR board and approved by the agency director or designee.

"Medically accepted indication" - Any use for a covered outpatient drug:

(1) Which is approved under the federal Food, Drug, and Cosmetic Act; or

(2) The use of which is supported by one or more citations included or approved for inclusion in any of the compendia of drug information, as defined in this chapter.

"Modified unit dose delivery system" (also known as blister packs or "bingo/punch cards") - A method in which each patient's medication is delivered to a nursing facility:

(1) In individually sealed, single dose packages or "blisters"; and

(2) In quantities for one month's supply, unless the prescriber specifies a shorter period of therapy.

"Multiple-source drug" - A drug for which there is at least one other drug product sold in the United States that is pharmaceutically equivalent and bioequivalent, as determined by the Food and Drug Administration (FDA).

"National drug code (NDC)" - The ((~~eleven~~)) 11-digit numerical code that includes the labeler code, product code, and package code.

"National rebate agreement" - The agreement developed by the Centers for Medicare and Medicaid Services (CMS) to implement section 1927 of the Social Security Act, and entered into by a manufacturer and the federal Department of Health and Human Services (DHHS).

"Noninnovator multiple-source drug" - A drug that is:

(1) A multiple-source drug that is not an innovator multiple-source drug or a single-source drug;

(2) A multiple-source drug marketed under an abbreviated new drug application (ANDA) or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 and was originally marketed under a new drug application (NDA); or

(4) Any drug that has not gone through a Food and Drug Administration (FDA) approval process but otherwise meets the definition of a covered outpatient drug.

If any of the drug products listed in this definition of a noninnovator multiple-source drug subsequently receive an NDA or ANDA approval from the FDA, the product's drug category changes to correlate with the new product application type.

"Nonpreferred drug" - A drug within a therapeutic class of drugs on the medicaid preferred drug list (medicaid PDL) that has not been selected as a preferred drug.

"Obsolete NDC" - A national drug code replaced or discontinued by the manufacturer or labeler.

"Over-the-counter (OTC) drugs" - Drugs that do not require a prescription before they can be sold or dispensed.

"Peer reviewed medical literature" - A research study, report, or findings regarding the specific use of a drug that has been submitted to one or more professional journals, reviewed by experts with appropriate credentials, and subsequently published by a reputable professional journal. A clinical drug study used as the basis for the publication must be a double blind, randomized, placebo or active control study.

"Pharmacist" - A person licensed in the practice of pharmacy by the state in which the prescription is filled.

"Pharmacy" - Every location licensed by the state board of pharmacy in the state where the practice of pharmacy is conducted.

"Pharmacy and therapeutic (P&T) committee" - The independent Washington state committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the medicaid agency or its designee, the committee may serve as the drug use review board provided for in WAC 182-530-4000.

"Point-of-sale (POS)" - A pharmacy claims processing system capable of receiving and adjudicating claims online.

"Practice of pharmacy" - The practice of and responsibility for:

(1) Accurately interpreting prescription orders;

(2) Compounding drugs;

(3) Dispensing, labeling, administering, and distributing of drugs and devices;

(4) Providing drug information to the client that includes, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices;

(5) Monitoring of drug therapy and use;

(6) Proper and safe storage of drugs and devices;

(7) Documenting and maintaining records;

(8) Initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for a pharmacist's practice by a practitioner authorized to prescribe drugs; and

(9) Participating in drug use reviews and drug product selection.

"Practitioner" - An individual who has met the professional and legal requirements necessary to provide a health care service, such as a physician, nurse, dentist, physical therapist, pharmacist, or other person authorized by state law as a practitioner.

"Preferred drug" - A drug within a therapeutic class of drugs on the medicaid preferred drug list (medicaid PDL) that has been selected as a preferred drug.

"Prescriber" - A physician, osteopathic physician/surgeon, dentist, nurse, physician assistant, optometrist, pharmacist, or other person authorized by law or rule to prescribe drugs. See WAC 246-863-100 for pharmacists' prescriptive authority.

"Prescription" - An order for drugs or devices issued by a practitioner authorized by state law or rule to prescribe drugs or devices, in the course of the practitioner's professional practice, for a legitimate medical purpose.

"Prescription drugs" - Drugs required by any applicable federal or state law or regulation to be dispensed by prescription only or that are restricted to use by practitioners only.

"Professional dispensing fee":

(1) The fee the medicaid agency or its designee pays pharmacists and dispensing providers for covered prescriptions. The fee pays for costs in excess of the ingredient cost of a covered outpatient drug when a covered outpatient drug is dispensed; and

(2) Includes only costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a medicaid beneficiary. Pharmacy and dispensing provider costs include, but are not limited to, reasonable costs associated with a prescriber's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the dispensing entity.

"Prospective drug use review (Pro-DUR)" - A process in which a request for a drug product for a particular client is screened, before the product is dispensed, for potential drug therapy problems.

"Reconstitution" - The process of returning a single active ingredient, previously altered for preservation and storage, to its approximate original state. Reconstitution is not compounding.

"Retrospective drug use review (Retro-DUR)" - The process in which drug utilization is reviewed on an ongoing periodic basis to identify patterns of fraud, abuse, gross overuse, or inappropriate or not medically necessary care.

"Single-source drug" - A drug produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA) with an approved new drug application (NDA) number issued by the FDA. This includes:

(1) A drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA; or

(2) A drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA).

For the purposes of this definition, an ANDA is not an NDA.

"Systematic review" - A specific and reproducible method to identify, select, and appraise all the studies that meet minimum quality standards and are relevant to a particular question. The results of the studies are then analyzed and summarized into evidence tables to be used to guide evidence-based decisions.

"Terminated NDC" - An ((~~eleven~~)) 11-digit national drug code (NDC) that is discontinued by the manufacturer for any reason. The NDC may be terminated immediately due to health or safety issues or it may be phased out based on the product's shelf life.

"Therapeutic alternative" - A drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage.

"Therapeutic class" - A group of drugs used for the treatment, remediation, or cure of a specific disorder or disease.

"Therapeutic interchange" - To dispense a therapeutic alternative to the prescribed drug when an endorsing practitioner who has indicated that substitution is permitted, prescribes the drug. See therapeutic interchange program (TIP).

"Therapeutic interchange program (TIP)" - The process developed by participating state agencies under RCW 69.41.190 and 70.14.050, to allow prescribers to endorse a Washington preferred drug list, and in most cases, requires pharmacists to automatically substitute a preferred, equivalent drug from the list.

"Therapeutically equivalent" - Drug products that contain different chemical structures but have the same efficacy and safety when administered to an individual, as determined by:

(1) Information from the Food and Drug Administration (FDA);

(2) Published and peer-reviewed scientific data;

(3) Randomized controlled clinical trials; or

(4) Other scientific evidence.

"Tiered dispensing fee system" - A system of paying pharmacies different dispensing fee rates, based on the individual pharmacy's total annual prescription volume and/or the drug delivery system used.

"True unit dose delivery" - A method in which each patient's medication is delivered to the nursing facility in quantities sufficient only for the day's required dosage.

"Unit dose drug delivery" - True unit dose or modified unit dose delivery systems.

"Usual and customary charge" - The fee that the provider typically charges the general public for the product or service.

"Washington preferred drug list (Washington PDL)" - The list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for purchase of drugs in state-operated health care programs.

"Wholesale acquisition cost" - Refers to either the actual wholesale cost paid by a wholesaler for drugs purchased from a manufacturer or a list price published as wholesale acquisition cost.

AMENDATORY SECTION (Amending WSR 17-07-001, filed 3/1/17, effective 4/1/17)

WAC 182-530-7000 Reimbursement. (1) The medicaid agency's reimbursement for a prescription drug dispensed through point-of-sale (POS) must not exceed the lesser of actual acquisition cost (AAC) plus a professional dispensing fee or the provider's usual and customary charge.

(2) The agency selects the sources for pricing information used to set ((~~POS~~)) AAC.

(3) The ((~~POS~~)) AAC is calculated as the lowest of:

(a) National average drug acquisition cost (NADAC);

(b) Maximum allowable cost (MAC);

(c) Federal upper limit (FUL);

(d) 340B ((~~Actual acquisition cost (340B AAC)~~)) MAC for covered outpatient drugs purchased, dispensed, or administered under section 340B of the Public Health Service (PHS) Act (see WAC 182-530-7900 for exceptions); or

(e) ((~~Automated maximum allowable cost (AMAC)~~)) Submitted ingredient cost.

(4) Where NADAC does not exist, other available reference prices from national sources such as wholesale acquisition cost, or average manufacturer price ((~~will~~)) may be used as the basis of the reimbursement.

(5) Where NADAC does not accurately reflect the actual acquisition costs in Washington state, a percentage adjustment to NADAC will be made to the reimbursement.

(6) The agency may set ((~~POS~~)) AAC for specified drugs ((~~or~~)), drug categories, or providers at a maximum allowable cost other than that determined in subsection (2) of this section based on specific product acquisition costs. The agency considers product acquisition costs in setting a rate for a drug or a class of drugs.

(7) The agency bases ((~~POS~~)) AAC drug reimbursement on the actual package size dispensed.

(8) The agency reimburses a pharmacy for the least costly dosage form of a drug within the same route of administration, unless the prescriber has designated a medically necessary specific dosage form or the agency has selected the more expensive dosage form as a preferred drug.

(9) If the pharmacy provider offers a discount, rebate, promotion, or other incentive which directly relates to the reduction of the price of a prescription to the individual nonmedicaid customer, the provider must similarly reduce its charge to the agency for the prescription.

(10) If the pharmacy provider gives an otherwise covered product for free to the general public, the pharmacy must not submit a claim to the agency.

(11) The agency does not reimburse for:

(a) Prescriptions written on presigned prescription blanks filled out by nursing facility operators or pharmacists;

(b) Prescriptions without the date of the original order;

(c) Drugs used to replace those taken from a nursing facility emergency kit;

(d) Drugs used to replace a physician's stock supply;

(e) Outpatient drugs, biological products, insulin, supplies, appliances, and equipment included in other reimbursement methods including, but not limited to:

(i) Diagnosis-related group (DRG);

(ii) Ratio of costs-to-charges (RCC);

(iii) Nursing facility daily rates;

(iv) Managed care capitation rates;

(v) Block grants; or

(vi) Drugs prescribed for clients who are on the agency's hospice program when the drugs are related to the client's terminal illness and related condition.

(f) Hemophilia and von Willebrand related products shipped to clients for administration in the home unless the products are provided through a qualified hemophilia treatment center of excellence (COE) as defined in WAC 182-531-1625.

AMENDATORY SECTION (Amending WSR 23-11-007, filed 5/4/23, effective 6/4/23)

WAC 182-530-7250 Reimbursement—Miscellaneous. (1) The medicaid agency reimburses for covered drugs, devices, and drug-related supplies provided or administered by nonpharmacy providers under specified conditions, as follows:

(a) The agency reimburses for drugs administered or prepared and delivered for individual use by an authorized prescriber during an office visit according to specific program rules found in:

(i) Chapter 182-531 WAC, Physician-related services;

(ii) Chapter 182-532 WAC, Reproductive health/family planning ((~~only~~)) programs; and

(iii) Chapter 182-540 WAC, Kidney disease program and kidney center services.

(b) Providers who are ((~~purchasers~~)) participating PHS-qualified covered entities under section 340B of the Public Health Services (PHS) ((~~discounted drugs~~)) Act must comply with PHS 340B program requirements and Washington medicaid requirements for 340B providers participating with medicaid. (See WAC 182-530-7900.)

(2) The agency may ((~~request~~)) require providers to submit a current invoice for the actual cost of the drug, device, or drug-related supply billed. If an invoice is ((~~requested~~)) required, the invoice must show the:

(a) Name of the drug, device, or drug-related supply;

(b) Drug or product manufacturer;

(c) NDC of the product or products;

(d) Drug strength;

(e) Product description;

(f) Quantity; and

(g) Cost, including any discounts or free goods associated with the invoice.

(3) The agency does not reimburse providers for the cost of vaccines obtained through the state department of health (DOH). The agency does pay physicians, advanced registered nurse practitioners (ARNP), and pharmacists a fee for administering the vaccine.

AMENDATORY SECTION (Amending WSR 17-07-001, filed 3/1/17, effective 4/1/17)

WAC 182-530-7300 Reimbursement—Requesting a change. Upon request from a ((~~pharmacy~~)) provider, the medicaid agency may reimburse at the provider's actual acquisition cost (((~~provider~~)) AAC) for a drug that would otherwise be reimbursed at maximum allowable cost (MAC) when:

(1) The availability of lower cost equivalents in the marketplace is severely curtailed and the price disparity between AAC for the drug and the MAC reimbursement affects clients' access; and

(2) An invoice documenting ((~~actual acquisition cost~~)) AAC relevant to the date the drug was dispensed is provided to the agency.

AMENDATORY SECTION (Amending WSR 21-08-021, filed 3/29/21, effective 5/1/21)

WAC 182-530-7900 Drugs purchased under the Public Health Service (PHS) Act. (1) ((~~Providers dispensing or administering 340B drugs to Washington apple health clients are required to submit their valid medicaid provider number(s) or national provider identification (NPI) number to the PHS health resources and services administration, office of pharmacy affairs. See WAC 182-530-7500 for information on the drug rebate program.~~

~~(2) Drugs purchased under section 340B of the Public Health Service (PHS) Act can be billed to Washington apple health only by PHS-qualified entities. The Washington medicaid rebate process excludes 340B claims from invoicing only when the drug is billed by a medicaid provider number or national provider identification (NPI) number listed on the PHS office of pharmacy affairs national medicaid exclusion file. See WAC 182-530-7500 for information on the drug rebate program.~~

~~(3) As part of participation in the 340B program, providers must submit a completed annual attestation form (HCA 13-0047) to the agency acknowledging that all claims for Washington apple health clients in both fee-for-service and managed care are subject to their respective 340B rules. Providers who fail to submit a completed attestation form to the agency may receive a compliance audit and be at risk of duplicate discounts.~~)) Providers registered and approved as PHS-qualified covered entities participate in the 340B program under their medicaid provider number or NPI listed on the quarterly medicaid exclusion file (MEF).

(2) PHS-qualified covered entities participating in the 340B program must follow federal and state 340B program requirements and applicable medicaid agency rules including, but not limited to, this chapter, chapters 182-501 and 182-502 WAC, and agency billing instructions.

(3) All claims submitted to Washington apple health through fee-for-service (FFS) or managed care for outpatient drugs purchased, dispensed, or administered by PHS-qualified covered entities participating in the 340B program:

(a) May be billed only by the PHS-qualified covered entity participating in the 340B program under their participating medicaid provider number or NPI listed in the quarterly medicaid exclusion file; and

(b) Are excluded from medicaid drug rebate invoicing. See WAC 182-530-7500 for information on the drug rebate program.

(4) With the exception of claim types identified in subsection (5) of this section, all ((~~340B purchased drugs under the medicaid fee-for-service program must be billed to the medicaid agency at the 340B actual acquisition cost (340B AAC)~~)) drugs purchased, dispensed, or administered by a PHS-qualified covered entity participating in the 340B program must be billed at the actual acquisition cost (AAC) when submitted through FFS to the agency.

(5) Exceptions to the ((~~340B~~)) AAC billing requirement are only made for:

(a) Outpatient hospital claims paid under the enhanced ambulatory payment group (EAPG) methodology (see WAC 182-550-7000); and

(b) Ambulatory surgery claims paid under payment groups methodology.

(6) As part of participation in the 340B program, providers must submit a completed annual attestation form (HCA 13-0047) to the agency acknowledging that all claims for Washington apple health clients in both FFS and managed care are subject to all applicable 340B rules. Providers who fail to submit a completed attestation form to the agency may receive a compliance audit and be at risk of duplicate discounts.

AMENDATORY SECTION (Amending WSR 17-07-001, filed 3/1/17, effective 4/1/17)

WAC 182-530-8000 Reimbursement method—Actual acquisition cost (AAC). The medicaid agency uses the following sources to determine ((~~point-of-sale~~)) actual acquisition cost (((~~POS~~)) AAC) including, but not limited to:

(1) National average drug acquisition cost (NADAC) published by the Centers for Medicare and Medicaid Services (CMS);

(2) Acquisition cost data made available to the agency by:

(a) Audit results from federal or state agencies;

(b) Other state health care purchasing organizations;

(c) Pharmacy benefit managers;

(d) Individual pharmacy providers participating in the agency's programs;

(e) Other third-party payers;

(f) Drug file databases; and

(g) Actuaries or other consultants.

AMENDATORY SECTION (Amending WSR 17-07-001, filed 3/1/17, effective 4/1/17)

WAC 182-530-8100 Reimbursement—Maximum allowable cost (MAC). (1) The medicaid agency establishes a maximum allowable cost (MAC) for ((~~a multiple-source drug which is available from at least two manufacturers/labelers~~)) covered outpatient drugs.

(2) The agency determines the MAC for ((~~a multiple-source~~)) covered outpatient drugs:

(a) When specific regional and local drug acquisition cost data is available, the agency:

(i) Identifies what products are available from wholesalers for each drug being considered for MAC pricing;

(ii) Determines pharmacy providers' approximate acquisition costs for these products; and

(iii) Establishes the MAC at a level which gives pharmacists access to at least one product from a manufacturer with a qualified rebate agreement (see WAC 182-530-7500(4)).

(b) When specific regional and local drug acquisition cost data is not available, the agency may estimate acquisition cost based on national pricing sources.

(3) The MAC established for ((~~a multiple-source~~)) covered outpatient drugs does not apply if the written prescription identifies that

a specific brand is medically necessary for a particular client. In such cases, the actual acquisition cost (AAC) for the particular brand applies, provided authorization is obtained from the agency as specified under WAC 182-530-3000.

(4) Except as provided in subsection (3) of this section, the agency reimburses providers for ((~~a multiple-source~~)) covered outpatient drugs at the lowest of the rates calculated under the methods listed in WAC 182-530-7000.

(5) The MAC established for ((~~a multiple-source~~)) covered outpatient drugs may vary by package size, including those identified as unit dose national drug codes (NDCs) by the manufacturer or manufacturers of the drug.

AMENDATORY SECTION (Amending WSR 19-09-052, filed 4/12/19, effective 5/13/19)

WAC 182-531-0050 Physician-related services definitions. The following definitions and abbreviations and those found in chapter 182-500 WAC, apply to this chapter.

((**"Acquisition cost"** - The cost of an item excluding shipping, handling, and any applicable taxes.))

"Actual acquisition cost" - See WAC 182-530-1050.

"Acute care" - Care provided for clients who are not medically stable. These clients require frequent monitoring by a health care professional in order to maintain their health status. See also WAC 246-335-015.

"Acute physical medicine and rehabilitation (PM&R)" - A comprehensive inpatient and rehabilitative program coordinated by a multidisciplinary team at ((an)) a medicaid agency-approved rehabilitation facility. The program provides ((twenty-four)) 24-hour specialized nursing services and an intense level of specialized therapy (speech, physical, and occupational) for a diagnostic category for which the client shows significant potential for functional improvement (see WAC 182-550-2501).

"Add-on procedure(s)" - Secondary procedure(s) that are performed in addition to another procedure.

"Admitting diagnosis" - The medical condition responsible for a hospital admission, as defined by the ICD diagnostic code.

"Advanced registered nurse practitioner (ARNP)" - A registered nurse prepared in a formal educational program to assume an expanded health services provider role in accordance with WAC 246-840-300 and 246-840-305.

"Allowed charges" - The maximum amount reimbursed for any procedure that is allowed by the medicaid agency.

"Anesthesia technical advisory group (ATAG)" - An advisory group representing anesthesiologists who are affected by the implementation of the anesthesiology fee schedule.

"Bariatric surgery" - Any surgical procedure, whether open or by laparoscope, which reduces the size of the stomach with or without bypassing a portion of the small intestine and whose primary purpose is the reduction of body weight in an obese individual.

"Base anesthesia units (BAU)" - A number of anesthesia units assigned to a surgical procedure that includes the usual preoperative, intraoperative, and postoperative visits. This includes the administration of fluids and/or blood incident to the anesthesia care, and interpretation of noninvasive monitoring by the anesthesiologist.

"Bundled services" - Services integral to the major procedure that are included in the fee for the major procedure. Bundled services are not reimbursed separately.

"Bundled supplies" - Supplies that are considered to be included in the practice expense RVU of the medical or surgical service of which they are an integral part.

"By report (BR)((,))" - See WAC 182-500-0015.

"Call" - A face-to-face encounter between the client and the provider resulting in the provision of services to the client.

"Cast material maximum allowable fee" - A reimbursement amount based on the average cost among suppliers for one roll of cast material.

"Center of excellence (COE)" - A hospital, medical center, or other health care provider that meets or exceeds standards set by the agency for specific treatments or specialty care.

"Centers for Medicare and Medicaid Services (CMS)((~~,~~))" - See WAC 182-500-0020.

"Certified registered nurse anesthetist (CRNA)" - An advanced registered nurse practitioner (ARNP) with formal training in anesthesia who meets all state and national criteria for certification. The American Association of Nurse Anesthetists specifies the national certification and scope of practice.

"Children's health insurance plan (CHIP)((~~,~~))" - See chapter 182-542 WAC.

"Clinical Laboratory Improvement Amendment (CLIA)" - Regulations from the U.S. Department of Health and Human Services that require all laboratory testing sites to have either a CLIA registration or a CLIA certificate of waiver in order to legally perform testing anywhere in the U.S.

"Conversion factors" - Dollar amounts the medicaid agency uses to calculate the maximum allowable fee for physician-related services.

"Covered service" - A service that is within the scope of the eligible client's medical care program, subject to the limitations in this chapter and other published WAC.

"CPT((~~,~~))" - See "current procedural terminology."

"Critical care services" - Physician services for the care of critically ill or injured clients. A critical illness or injury acutely impairs one or more vital organ systems such that the client's survival is jeopardized. Critical care is given in a critical care area, such as the coronary care unit, intensive care unit, respiratory care unit, or the emergency care facility.

"Current procedural terminology (CPT)" - A systematic listing of descriptive terms and identifying codes for reporting medical services, procedures, and interventions performed by physicians and other practitioners who provide physician-related services. CPT is copyrighted and published annually by the American Medical Association (AMA).

"Emergency medical condition(s)((~~,~~))" - See WAC 182-500-0030.

"Emergency services" - Medical services required by and provided to a patient experiencing an emergency medical condition.

"Evaluation and management (E&M) codes" - Procedure codes that categorize physician services by type of service, place of service, and patient status.

"Expedited prior authorization" - The process of obtaining authorization that must be used for selected services, in which providers use a set of numeric codes to indicate to the medicaid agency which acceptable indications, conditions, diagnoses, and/or criteria are applicable to a particular request for services.

"Experimental" - A term to describe a health care service that lacks sufficient scientific evidence of safety and effectiveness. A service is not "experimental" if the service:

(a) Is generally accepted by the medical profession as effective and appropriate; and

(b) Has been approved by the federal Food and Drug Administration or other requisite government body, if such approval is required.

"Federally approved hemophilia treatment center" - A hemophilia treatment center (HTC) that:

(a) Receives funding from the U.S. Department of Health and Human Services, Maternal and Child Health Bureau National Hemophilia Program;

(b) Is qualified to participate in 340B discount purchasing as an HTC. See WAC 182-530-7900;

(c) Has a U.S. Center for Disease Control (CDC) and prevention surveillance site identification number and is listed in the HTC directory on the CDC website;

(d) Is recognized by the Federal Regional Hemophilia Network that includes Washington state; and

(e) Is a direct care provider offering comprehensive hemophilia care consistent with treatment recommendations set by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation in their standards and criteria for the care of persons with congenital bleeding disorders.

"Fee-for-service((,))" - See WAC 182-500-0035.

"Flat fee" - The maximum allowable fee established by the agency for a service or item that does not have a relative value unit (RVU) or has an RVU that is not appropriate.

"Geographic practice cost index (GPCI)" - As defined by medicare, means a medicare adjustment factor that includes local geographic area estimates of how hard the provider has to work (work effort), what the practice expenses are, and what malpractice costs are. The GPCI reflects one-fourth the difference between the area average and the national average.

"Global surgery reimbursement((,))" - See WAC 182-531-1700.

"HCPCS Level II" - Health care common procedure coding system, a coding system established by Centers for Medicare and Medicaid Services (CMS) to define services and procedures not included in CPT.

"Health care financing administration common procedure coding system (HCPCS)" - The name used for the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) codes made up of CPT and HCPCS level II codes.

"Health care team" - A group of health care providers involved in the care of a client.

"Hospice" - A medically directed, interdisciplinary program of palliative services which is provided under arrangement with a Title XVIII Washington licensed and certified Washington state hospice for terminally ill clients and the clients' families.

"ICD((,))" - See "International Classification of Diseases."

"Informed consent" - That an individual consents to a procedure after the provider who obtained a properly completed consent form has done all ((~~of~~)) the following:

(a) Disclosed and discussed the client's diagnosis;

(b) Offered the client an opportunity to ask questions about the procedure and to request information in writing;

(c) Given the client a copy of the consent form;

(d) Communicated effectively using any language interpretation or special communication device necessary per 42 C.F.R. Chapter IV 441.257; and

(e) Given the client oral information about all ((~~of~~)) the following:

(i) The client's right to not obtain the procedure, including potential risks, benefits, and the consequences of not obtaining the procedure;

(ii) Alternatives to the procedure including potential risks, benefits, and consequences; and

(iii) The procedure itself, including potential risks, benefits, and consequences.

"Inpatient hospital admission" - An admission to a hospital that is limited to medically necessary care based on an evaluation of the client using objective clinical indicators, assessment, monitoring, and therapeutic service required to best manage the client's illness or injury, and that is documented in the client's medical record.

"International Classification of Diseases (ICD)" - The systematic listing that transforms verbal descriptions of diseases, injuries, conditions, and procedures into numerical or alphanumerical designations (coding).

"Investigational" - A term to describe a health care service that lacks sufficient scientific evidence of safety and effectiveness for a particular condition. A service is not "investigational" if the service:

(a) Is generally accepted by the medical professional as effective and appropriate for the condition in question; or

(b) Is supported by an overall balance of objective scientific evidence, that examines the potential risks and potential benefits and demonstrates the proposed service to be of greater overall benefit to the client in the particular circumstance than another generally available service.

"Life support" - Mechanical systems, such as ventilators or heart-lung respirators, which are used to supplement or take the place of the normal autonomic functions of a living person.

"Limitation extension((~~,~~))" - See WAC 182-501-0169.

"Long-acting reversible contraceptive (LARC)" - Subdermal implants and intrauterine devices (IUDs).

"Maximum allowable fee" - The maximum dollar amount that the medicaid agency will reimburse a provider for specific services, supplies, and equipment.

"Medically necessary((~~,~~))" - See WAC 182-500-0070.

"Medication assisted treatment (MAT)" - The use of Food and Drug Administration-approved medications that have published evidence of effectiveness, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders.

"Medicare clinical diagnostic laboratory fee schedule" - The fee schedule used by medicare to reimburse for clinical diagnostic laboratory procedures in the state of Washington.

"Medicare physician fee schedule database (MPFSDB)" - The official CMS publication of the medicare policies and RVUs for the RBRVS reimbursement program.

"Medicare program fee schedule for physician services (MPFSPS)" - The official CMS publication of the medicare fees for physician services.

"Mentally incompetent" - A client who has been declared mentally incompetent by a federal, state, or local court.

"Modifier" - A two-digit alphabetic ((~~and/~~)) or numeric, or both, identifier that is added to the procedure code to indicate the type of service performed. The modifier provides the means by which the reporting physician can describe or indicate that a performed service or procedure has been altered by some specific circumstance but not changed in its definition or code. The modifier can affect payment or be used for information only. Modifiers are listed in fee schedules.

"Outpatient((~~,~~))" - See WAC 182-500-0080.

"Peer-reviewed medical literature" - A research study, report, or findings regarding a medical treatment that is published in one or more reputable professional journals after being critically reviewed

by appropriately credentialed experts for scientific validity, safety, and effectiveness.

"Physician care plan" - A written plan of medically necessary treatment that is established by and periodically reviewed and signed by a physician. The plan describes the medically necessary services to be provided by a home health agency, a hospice agency, or a nursing facility.

"Physician standby" - Physician attendance without direct face-to-face client contact and which does not involve provision of care or services.

"Physician's current procedural terminology((~~,~~))" - See "current procedural terminology (CPT)."

"PM&R((~~,~~))" - See acute physical medicine and rehabilitation.

"Podiatric service" - The diagnosis and medical, surgical, mechanical, manipulative, and electrical treatments of ailments of the foot and ankle.

((~~**"Point-of-sale (POS) actual acquisition cost (AAC)" - The agency determined rate paid to pharmacies through the POS system, which is intended to reflect pharmacy providers' actual acquisition cost.**~~))

"Pound indicator (#)" - A symbol (#) indicating a CPT procedure code listed in the medicaid agency's fee schedules that is not routinely covered.

"Preventive" - Medical practices that include counseling, anticipatory guidance, risk factor reduction interventions, and the ordering of appropriate laboratory and diagnostic procedures intended to help a client avoid or reduce the risk or incidence of illness or injury.

"Prior authorization((~~,~~))" - See WAC 182-500-0085.

"Professional component" - The part of a procedure or service that relies on the provider's professional skill or training, or the part of that reimbursement that recognizes the provider's cognitive skill.

"Prognosis" - The probable outcome of a client's illness, including the likelihood of improvement or deterioration in the severity of the illness, the likelihood for recurrence, and the client's probable life span as a result of the illness.

"Prolonged services" - Face-to-face client services furnished by a provider, either in the inpatient or outpatient setting, which involve time beyond what is usual for such services. The time counted toward payment for prolonged E&M services includes only face-to-face contact between the provider and the client, even if the service was not continuous.

"Provider((~~,~~))" - See WAC 182-500-0085.

"Radioallergosorbent test" or **"RAST"** - A blood test for specific allergies.

"RBRVS((~~,~~))" - See resource based relative value scale.

"RBRVS RVU" - A measure of the resources required to perform an individual service or intervention. It is set by medicare based on three components - Physician work, practice cost, and malpractice expense. Practice cost varies depending on the place of service.

"Reimbursement" - Payment to a provider or other agency-approved entity who bills according to the provisions in WAC 182-502-0100.

"Reimbursement steering committee (RSC)" - An interagency work group that establishes and maintains RBRVS physician fee schedules and other payment and purchasing systems utilized by the medicaid agency and the department of labor and industries.

"Relative value guide (RVG)" - A system used by the American Society of Anesthesiologists for determining base anesthesia units (BAUs).

"Relative value unit (RVU)" - A unit that is based on the resources required to perform an individual service or intervention.

"Resource based relative value scale (RBRVS)" - A scale that measures the relative value of a medical service or intervention, based on the amount of physician resources involved.

"RSC RVU" - A unit established by the RSC for a procedure that does not have an established RBRVS RVU or has an RBRVS RVU deemed by the RSC as not appropriate for the service.

"RVU((~~,~~))" - See relative value unit.

"Stat laboratory charges" - Charges by a laboratory for performing tests immediately. "Stat" is an abbreviation for the Latin word "statim," meaning immediately.

"Sterile tray" - A tray containing instruments and supplies needed for certain surgical procedures normally done in an office setting. For reimbursement purposes, tray components are considered by CMS to be nonroutine and reimbursed separately.

"Technical advisory group (TAG)" - An advisory group with representatives from professional organizations whose members are affected by implementation of RBRVS physician fee schedules and other payment and purchasing systems utilized by the agency and the department of labor and industries.

"Technical component" - The part of a procedure or service that relates to the equipment set-up and technician's time, or the part of the procedure and service reimbursement that recognizes the equipment cost and technician time.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

WAC 182-531-1200 Physician office medical supplies. (1) Refer to ((~~RBRVS~~)) the medicaid agency's published physician-related services/health care professional services billing ((~~instructions~~)) guide for a list of:

(a) Supplies that are a routine part of office or other outpatient procedures and that cannot be billed separately; and

(b) Supplies that can be billed separately and that the ((~~department~~)) medicaid agency considers nonroutine to office or outpatient procedures.

(2) The ((~~department~~)) agency reimburses at actual acquisition cost certain supplies under ((~~fifty dollars~~)) $50 that do not have a maximum allowable fee listed in the fee schedule. The provider must retain invoices for these items and make them available to the ((~~department~~)) agency upon request.

(3) Providers must submit invoices for items costing ((~~fifty dollars~~)) $50 or more.

(4) The ((~~department~~)) agency reimburses for **sterile tray** for certain surgical services only. Refer to the fee schedule for a list of covered items.

AMENDATORY SECTION (Amending WSR 17-04-039, filed 1/25/17, effective 2/25/17)

WAC 182-531-1450 Radiology physician-related services. (1) The medicaid agency reimburses radiology services subject to the limitations in this section and under WAC 182-531-0300.

(2) The agency does not make separate payments for contrast material. The exception is low osmolar contrast media (LOCM) used in intrathecal, intravenous, and intra-arterial injections. Clients receiving these injections must have one or more of the following conditions:

(a) A history of previous adverse reaction to contrast material. An adverse reaction does not include a sensation of heat, flushing, or a single episode of nausea or vomiting;

(b) A history of asthma or allergy;

(c) Significant cardiac dysfunction including recent or imminent cardiac decompensation, severe arrhythmias, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension;

(d) Generalized severe debilitation;

(e) Sickle cell disease;

(f) Preexisting renal insufficiency; and/or

(g) Other clinical situations where use of any media except LOCM would constitute a danger to the health of the client.

(3) The agency reimburses separately for radiopharmaceutical diagnostic imaging agents for nuclear medicine procedures. Providers must submit invoices for these procedures when requested by the agency, and reimbursement is at actual acquisition cost.

(4) The agency reimburses general anesthesia for radiology procedures. See WAC 182-531-0300.

(5) The agency reimburses radiology procedures in combination with other procedures according to the rules for multiple surgeries. See WAC 182-531-1700. The procedures must meet all of the following conditions:

(a) Performed on the same day;

(b) Performed on the same client; and

(c) Performed by the same physician or more than one member of the same group practice.

(6) The agency reimburses consultation on X-ray examinations. The consulting physician must bill the specific radiological X-ray code with the appropriate professional component modifier.

(7) The agency reimburses for portable X-ray services furnished in the client's home or in nursing facilities, limited to the following:

(a) Chest or abdominal films that do not involve the use of contrast media;

(b) Diagnostic mammograms; and

(c) Skeletal films involving extremities, pelvis, vertebral column, or skull.